

Attorney Docket No.: DEX-0176
Inventors: Ali et al.
Serial No.: 09/787,844
Filing Date: August 6, 2001
Page 7

REMARKS

Claims 1-9 and 12-21 are pending in the instant patent application. Claims 1-7 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 8, 9 and 12-21 have been rejected. Claims 8, 9, 13, 14, 15, 17, 18, 19 and 21 have been amended. Claims 12, 16 and 20 have been canceled in light of the amendments to claims 8, 14, and 18. New claims 22 through 33 have been added. Support for these amendments is provided by claims 12, 16 and 20 and teaching in the specification, for example at page 8, lines 31-32 and data presented in Example 2 at pages 17 through 24, pages 14 through 16, and pages 18 through 25. Thus no new matter is added by these amendments. Reconsideration and withdrawal of the rejections is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed May 5, 2003. Thus, in an earnest effort to advance the prosecution, Applicants have canceled without prejudice, non-elected claims 1-7. In light of the finality of this Restriction Requirement, Applicants reserve the right to

Attorney Docket No.: DEX-0176
Inventors: Ali et al.
Serial No.: 09/787,844
Filing Date: August 6, 2001
Page 8

file a divisional application to the canceled subject matter.

II. Rejection of Claims 8, 9 and 12-21 under 35 U.S.C. 112, second paragraph

Claims 8, 9 and 12-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular the Examiner suggests that the metes and bounds of recitation of "a Pro104 polypeptide" is not clear.

Thus, in an earnest effort to advance the prosecution, Applicants have deleted this phrase and amended the claims to be drawn simply to Pro104. What is meant by the term "Pro104" is clear and definite in light of teachings of the specification at pages 18 through 25. Thus, the claims as amended, when read in light of teachings of the specification as required by MPEP 2173.03, meet the requirements of 35 U.S.C. 112, second paragraph.

Claims 8, 9 and 12 and 13 are also rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps. In particular the Examiner suggests that the omitted steps are detection and

Attorney Docket No.: DEX-0176
Inventors: Ali et al.
Serial No.: 09/787,844
Filing Date: August 6, 2001
Page 9

determination steps to accomplish the purpose in the preamble of the claims.

Accordingly, in an earnest effort to advance the prosecution and in accordance with teachings at page 14 through 16 of the specification, Applicants have amended the claims to include detection/determination steps.

No new matter is added by these amendments.

Withdrawal of these rejections under 35 U.S.C. 112, second paragraph is respectfully requested.

III. Rejection of Claims 8, 9, and 12-21 under 35 U.S.C.

112, first paragraph - Written Description

Claims 8, 9 and 12-21 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner suggests that the definition of antibodies to include aptamers and single-stranded means that the claims are interpreted as being drawn to a method of using a genus of antibodies that specifically binds to SEQ ID NO:2, wherein the genus includes aptamers and single-stranded oligonucleotides. The Examiner has acknowledged that the recitation of "antibody" as understood by the art i.e. IgG, IgM, etc. does not lack written description. However, the Examiner suggests that

Attorney Docket No.: DEX-0176
Inventors: Ali et al.
Serial No.: 09/787,844
Filing Date: August 6, 2001
Page 10

the specification lacks written description for aptamers and single-stranded oligonucleotides.

While Applicants respectfully disagree with the Examiner, in an earnest effort to advance the prosecution of this case, the claims have been amended to state that the antibodies are polyclonal or monoclonal antibodies. Support for this amendment is provided in claims 12, 16, 20, now canceled.

Withdrawal of this rejection under 35 U.S.C. 112, first paragraph, is therefore respectfully requested.

IV. Rejection of Claims 8, 9 and 12-21 under 35 U.S.C. 112, first paragraph - Lack of Enablement

Claims 8, 9 and 12-21 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

In particular, the Examiner suggests that it requires undue experimentation to practice the instantly claimed invention because "it is seemingly impossible to use an antibody that specifically binds to a protein (SEQ ID NO:2) that does not exist in vivo and/or is not expressed in vivo."

Further, the Examiner suggests that the instant specification fails to teach whether SEQ ID NO:2 or a

Attorney Docket No.: DEX-0176
Inventors: Ali et al.
Serial No.: 09/787,844
Filing Date: August 6, 2001
Page 11

protein encoded by SEQ ID NO:1 is over-expressed in a gynecologic cancer. The Examiner suggests that in order to use the instant claimed invention, one has to perform experimentation involving a large number of clinical samples from gynecologic cancers to determine whether the protein encoded by SEQ ID NO:1 is over-expressed because Hooper et al. suggests that the protein encoded by instant SEQ ID NO:1 might be a tumor suppressor instead of a tumor antigen. The Examiner also cites references by Alberts et al., Shantz and Pegg et al., McClean and Hill, and Fu et al. in support of the suggestion that in the absence of a disclosure in the specification of a correlation between protein over-expression and over-expression of mRNA levels, the predictability of protein translation is not solely contingent on mRNA expression due to the multitude of homeostatic factors affecting transcription and translation.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that undue experimentation is required to use an antibody that specifically binds to the amino acid sequence of a polypeptide encoded by SEQ ID NO:1 depicted in the instant application as SEQ ID NO:2. Applicants in no way assert that that the polypeptide encoded by SEQ ID NO:1 and depicted in the instant

Attorney Docket No.: DEX-0176
Inventors: Ali et al.
Serial No.: 09/787,844
Filing Date: August 6, 2001
Page 12

application as SEQ ID NO:2 is a "protein existing in vivo". As acknowledged by the Examiner in the rejection it is well known in the art that in vivo translated proteins have Met as the first amino acid. One of skill in the art can thus routinely review the encoded amino acid sequence set forth in SEQ ID NO:2, without any undue experimentation, to determine the related in vivo translated protein or portions thereof to which antibodies should be raised particularly in light of teachings in the specification at page 25 regarding the 273 amino acid active protease domain. Claims 13, 17 and 21 have been amended in accordance with this teaching.

Further, claims of the instant application are drawn to methods for use of antibodies against Pro104 in gynecologic cancers. Thus, teachings of Hooper et al. relating to testicular cancer are not relevant to the instant claimed invention, particularly since completely different patients populations, females in the instant invention versus males in Hooper et al. are involved.

Finally, MPEP 2107.02 and In re Gaubert, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975) are clear; to maintain a lack of utility rejection a showing supported by specific evidence of a flaw in the logic upon which the utility is based is required by the Examiner. None of the references cited by the Examiner relate in any way to Pro104 and thus

Attorney Docket No.: DEX-0176
Inventors: Ali et al.
Serial No.: 09/787,844
Filing Date: August 6, 2001
Page 13

are inadequate to provide any showing of lack of utility with respect to the instant claimed invention.

In contrast, Applicants are providing herewith a copy of a poster (Abstract Number A215) presented on November 18, 2003 at the AACR-NCI-EORTC 2003 International Conference on "Molecular Targets and Cancer Therapeutics discovery, biology, and clinical applications". This poster provides confirming data in accordance with teachings of the instant specification that antibodies against Pro104 target gynecologic cancer cells as compared to normal tissue and can be used to image gynecologic cancer cells and deliver agents to gynecologic cancer cells as claimed.

Any further maintenance of this rejection, without some showing supported by specific evidence by the Examiner of any flaw in the logic upon which the utility described herein is based, is clearly improper. See MPEP 2107.02 and In re Gaubert, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975).

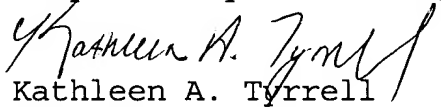
Withdrawal of this rejection under 35 U.S.C. 101 and 112, first paragraph is therefore respectfully requested.

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Attorney Docket No.: DEX-0176
Inventors: Ali et al.
Serial No.: 09/787,844
Filing Date: August 6, 2001
Page 14

Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A. Tyrrell
Reg. No. 38,350

Date: August 23, 2004

LICATA & TYRRELL P.C.
66 E. Main Street
Marlton, New Jersey 08053
(856) 810-1515